11. (Amended) The kit of claim 10, wherein the amount of human growth hormone is provided in intravenous unit form in doses of up to 0.5 mg per day.

14. (Amended) A kit for treating symptoms associated with multiple sclerosis comprising human growth hormone and at least one of the supplemental hormones selected from the group consisting of sex hormone, melatonin hormone, adrenal hormone, thyroid hormone, and thymus hormone, the kit for establishing a regimen for the replenishment of the human growth hormone and the at least one of the supplemental hormones to physiological levels associated with the second or third decades of an average human subject.

15. (Amended) The kit of claim 14, wherein the amount of human growth hormone is provided in intravenous unit form in doses of up to 0.5 mg per day.

REMARKS

In response to the above-identified Office Action, Applicant amends the application and seeks reconsideration thereof. In this response, Applicant amends Claims 11, 14 and 15. Accordingly, Claims 10-17 are pending.

Attached hereto is a marked-up version of the changes made to the Claims by the current Amendment. The attachment is captioned, "Version With Markings To Show Changes Made."

Applicant notes that the amendment to Claims 11 and 15 are not limiting in that they merely substitute the phrase, "up to" for the phrase, "less than." The phrase, "up to" has been held by the Court in *In re Mochel*, 176 USPQ 194 to include zero as a lower limit. The prior statement "less than" as a practical matter has a lower limit of zero since it is not practical to have a negative amount in a recitation of a composition. When read in conjunction with Claims 10 and 14 dependent Claims 11 and 15 regardless of how framed comprise an amount of hGH between zero and 0.5 mg.

I. Claims Rejected Under 35 U.S.C. § 112

The Office rejected Claims 10-17 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant respectfully disagrees.

The Office rejected Claim 10 stating the term, "treating symptoms associated with multiple sclerosis" renders the claim indefinite as to the symptom(s) being treated. Applicant submits definiteness of claim language must be analyzed, not in a vacuum, but in light of: the content of the particular application disclosure; the teachings of the prior art; and the claim interpretation that will be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. The Application as filed contained a brief description of mild and severe symptoms suffered by victims of multiple sclerosis, see page 2, lines 8-17. The Application as filed then goes on to give case histories further describing the recognizable symptoms of multiple sclerosis, see page 17, line 20 and page 19, line 1. Applicant respectfully submits reading the claims in light of the specification brings definiteness to the phrase, "treating symptoms associated with multiple sclerosis."

The Office states the terms, "predetermined physiological levels" renders Claims 10-13 indefinite and the phrase, "physiological levels associated with the second or third decades of an average human subject" renders Claims 14-17 indefinite. Applicant respectfully disagrees. An example of the phrase, "predetermined physiological levels" is exemplified in Table 1 of the Specification as filed. Physiological levels of an individual between for example, the age of 11 and 30 (second and third decades of life), although possibly subject to some debate regarding precision, are generally known by those of skill in the art. Table 1 lists Applicant's opinion of the optimum levels of various hormones of both sexes in the second or third decade at the time the Application was filed. The plethora of various quantities of various hormones illustrated in Table 1 make recitation of each level of each hormone in a male or female impractical in a single claim. Applicant

respectfully submits that the claim read in combination with the Specification renders the phrase, "predetermined physiological levels" sufficiently definite.

The Office rejected Claims 11 and 15 because the term "less than" is a relative term and renders the term indefinite. Applicant has amended Claims 11 and 15 to substitute the phrase, "up to" for the phrase "less than." Applicant respectfully submits these next Claims 11 and 15 definite as to the claims metes and bounds.

The Office rejected Claims 10-17 as improper kit claims. The Office states the claim lacks a proper label that instructs the user in various minor aspects of the method of using the composition. Applicant respectfully submits while these minor aspects of method of use are variations on details of administering the composition of the claims; the claims as written are sufficiently definite to describe the invention for purposes of patenting.

For at least these reasons, Applicant respectfully requests the Office withdraw its rejection of Claims 10-17 under 35 U.S.C. § 112, second paragraph.

2. Claims Rejected Under 35 U.S.C. § 103

The Office rejected Claims 10 though 17 under 35 U.S.C. § 103(a) as being unpatentable over Danielov, U.S. Patent No. 5,885,974 (hereinafter "Danielov"). Applicant respectfully disagrees.

In order to render a claim obvious, the relied upon reference must teach or suggest every limitation of the claim such that the invention as a whole would have been obvious at the time the invention was made to one skilled in the art. Claim 10 recites the limitation establishing a regimen for replenishment of human growth hormone and the at least one of the supplemental hormones to predetermined physiological levels. Claim 14 recites the limitation establishing a regimen for the replenishment of the human growth hormone and the at least one of the supplemental hormones to physiological levels associated with the second or third decade of an average human subject. Reading these claim limitations in combination with the specification which at Table 1 describes optimal or

predetermined physiological levels for the hormones and the average peak levels for the hormones which are present in adult humans at natural ages of optimal health, vigor and potency, usually in the second and third decades of the average life span. It may be seen from the combination of the claims and the specifications that the hormone measurements envisioned by the instant claims are those in the bloodstream.

In making the rejection, the Office relies on Danielov to teach the compositions and kits comprising a human growth hormone, progesterone, luteinizing hormone and various other hormones for treating a patient. See col. 14, lines 1-28. Furthermore, the Office states the content of the commercial kits comprising somatotropin and sex hormones are shown at column 20, lines 15+. Finally, the Office states the claims are drawn to a kit comprising a somatotropin, luteinizing hormone and thyrotropic hormone among others (claim 9). See the entire document. However, the Danielov patent discloses providing compositions useful in the treatment of various ailments of both normal and diseased skin and scalp using bioactive complexes in a novel delivery system (col. 5, lines 46-50). A novel delivery system of Danielov is useful as a topical and parenteral vehicle and as a vehicle for topical application of other skin treating agents. See col. 5, lines 22-30.

According to Applicant's understanding, Danielov does not disclose adjusting multiple hormone levels in the bloodstream of a human using various combinations and kits of hormones. Thus, Danielov fails to teach, suggest or motivate towards "replenishing hormone levels to predetermined physiological levels" and "physiological levels" associated with the second or third decades of an average human subject." The failure of Danielov to teach, suggest or motivate towards these predetermined physiological levels is fatal to the asserted rejection. Accordingly, Applicant respectfully requests withdrawal of the rejection of Claim 10 and 14.

Claims 11-13 are dependent on independent Claim 10 and Claims 15-17 are dependent on Independent Claim 14. The dependent claims contain all the limitations of their respective independent claims. Thus, Applicant respectfully submits dependent Claims 11-13 and 15-17 are not obvious over Danielov for at least the same reasons as independent Claims 10 and 14. Accordingly, Applicant respectfully requests withdraw of the rejections of Claims 10-17 under 35 U.S.C. § 103(a) as being obvious over Danielov.

3. Obviousness Type Double-Patenting

The Office rejected Claims 10-17 under the judicially created doctrine of obviousness type double-patenting as being unpatentable over Claims 26-34 of U.S. Patent No. 5,855,920 (hereinafter '920). The Office states that although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully described in the patent and is covered by the patent as shown in the specification in the claims. The Applicant respectfully disagrees.

The Claims of the '920 Patent are directed towards the method of increasing a life expectancy and life span by determining the level of human growth hormone and at least two supplemental hormones that are optimum and establishing a regimen for maintenance of the level of human growth hormone and supplemental hormones at optimal or "predetermined physiological levels". Claim 10 as filed and amended Claim 14 each recite the limitations of a "kit for treating symptoms associated with multiple sclerosis". The instant claims are thus directed towards a kit related to a hormone regimen that is useful in treating symptoms associated with multiple sclerosis as described in the specification as filed. Applicant respectfully submits that these hormonal replacement regimens being useful for treating symptoms of multiple sclerosis is an unexpected result for a composition directed towards increasing life expectancy and life span. Thus, it would not be obvious to one of ordinary skill in the art to treat symptoms associated with

multiple sclerosis with the kit and compositions of the '920 patent. The failure of the '920 patent to teach, suggest or motivate towards treating symptoms associated multiple sclerosis with its composition, is fatal to the asserted rejection. Therefore, Applicant respectfully submits that Claims 10 and 14 are not obvious over Claims 26-34 of the '920 patent reference.

Claims 11-13 depend on independent Claim 10 and Claims 15-17 depend on independent Claim 14 and contain all the limitations thereof. Applicant respectfully submits dependent Claims 11-13 and 15-17 are not obvious over Claims 26-34 of the 920 reference for at least the same reasons as the independent claims described above. Accordingly, Applicant respectfully requests withdraw of the obviousness-type double patenting of claims 10-17.

CONCLUSION

In view of the foregoing, it is believed that all claims all pending (1) are in proper form, (2) are neither obvious nor anticipated by the relied upon art of record, and (3) are in condition for allowance. A Notice of Allowance is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the Application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 207-3800.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to deposit account 02-2666 or any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly, extension of time fees.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN, LLP

Dated: 12/6/01

William Thomas Babbitt, Reg. No. 39,591

12400 Wilshire Blvd., Seventh Floor
Los Angeles, California 90025
(310) 207-3800

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on 12-6-01.

Diane Martinez — December 6, 2001 [Date]